REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Consideration and entry of this amendment is respectfully requested as it brings the application into condition for an allowance or in better form for consideration on appeal. The amendment does not raise any substantial new issues that would require any burdensome search by the Examiner.

A. Amendments to the Claims

Claims 44-52 and 73 are pending in this application.

Claims 44, 47, 48, 49, 51, and 52 were amended to clarify the scope of the invention. Claim 74 is canceled. Support for all of the amendments can be found in the application as originally filed. Specific support for amendment can be found, for instance, on page 5, last paragraph; page 11, lines 9-12; page 13, 2nd full paragraph; page 19, last paragraph to page 20, first paragraph; page 21, lines 11-29; Example 1, page 23, lines 23-26; Example 2, page 24-26; and Example 4 on pages 28-31. Accordingly, no new matter has been added to this application as a result of the amendments to the claims.

B. Claim Objections

Claim 44 is objected to for having a period at the end of line 4 of part (c). In light of the claim amendment removing the period from part (c), Applicants submit that the objection is now moot.

D. The Claims Are Supported by the Written Description

1. Paragraph 13 of the Office Action Mailed February 15, 2007

Claim 44 is rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. The Examiner complains that the claim language "separately determining presence or amount of the signal generating group bound to the first or the second test areas" is not supported by the specification. Applicants traverse the rejection.

Specifically, the Examiner asserts that although the specification supports a method where the positive result is obtained in one or more test areas, a method where the presence or amount of the signal generating group is determined in only one of the test areas is not supported.

The Examiner's assertion is misplaced. The phrase "bound to the first or the second test areas" modifies the immediate preceding object "the signal generating group," but not the action "separately determining." The specification supports a method for detection wherein the signal generating group binds to the first or the second test area. See Example 1, pages 22-23 of the application. Current amendment made to claim 44(c) further clarifies the scope of the claim. The amended claim 44 is directed to a method for simultaneous separate multiepitope detection of an analyte wherein a signal generating group binds to the first test area or the second test areas or the first and second test areas; wherein the presence or amount of the signal generating group is determined on both the first and second test areas; and wherein a positive result obtained on one test area is sufficient for indicating the presence of the analyte in the sample. The amended claim 44 is fully supported by the text throughout the specification, for instance, in Example 1 on pages 22-24 of the application. Thus, Applicants submit that the amendment has rendered the rejection moot.

2. Paragraph 14 of the Office Action Mailed February 15, 2007

Claim 74 stands rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. Claim 74 is now canceled. The cancellation of claim 74 has rendered this rejection moot.

3. Paragraph 15 of the Office Action Mailed February 15, 2007

Claims 48 and 51-52 stand rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. The Examiner acknowledges that the application supports the third receptor that binds specifically to the analyte; however, the Examiner asserts that the recitation of "the third receptor that binds specifically with the epitope(s) of the analyte" is not supported by the application. Applicants respectfully traverse the rejection but nevertheless amended the claims. Applicants submit that the present amendments to claims 48 and 51-52 obviate this rejection.

4. Paragraph 16 of the Office Action Mailed February 15, 2007

Claims 44 and 49 stand rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. Specifically, the Examiner asserts that a single application of the sample that simultaneously contacts the first and second spatially separate test areas is not supported. Applicants respectfully traverse this rejection. Nevertheless, Applicants have amended the claims to delete the term "simultaneously." Thus, the rejection is now moot.

E. The Claims Are Not Indefinite

1. Paragraph 19 of the Office Action Mailed February 15, 2007

Claim 44 stands rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for the use of the phrase "separately determining." Specifically, the Examiner asserts that "separate" determination of the signal generating group that binds to only one test area is indefinite. Applicants traverse the rejection.

Claim 44 is directed to a method for detection wherein the signal generating group binds to one or both of the first and second test areas; wherein the presence and amount of the signal generating group on both the first and second test areas are separately determined; and wherein the positive result obtained from only one test area is sufficient to indicate the presence of the analyte in the sample. The amendment to claim 44 further clarifies the scope of the claim. Because the first test area and the second test area are spatially separated, the presence and amount of the signal generating group on the test areas are spatially separately determined. Applicants submit that claim 44 is not indefinite, and request withdrawal of the rejection.

2. Paragraph 20 of the Office Action Mailed February 15, 2007

The Examiner maintains the rejection against claims 44-52, and 73-74 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for using the term "analyte." Specifically, the Examiner asserts that the term as used in the claims refers to "a heterogeneous population of different molecules," which is different from the alleged accepted meaning of "a single

molecule." The Examiner further alleges that Applicants did not put one of skill in the art on notice of Applicants' intended use of the term. Applicants respectfully disagree. Claim 74 is now canceled. The cancellation has rendered the rejection moot.

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. MPEP §2111.01. However, the meaning of words used in a claim is not construed in a lexicographic vacuum, but in the context of the specification and drawings. *Toro Co. v. While Consolidated Industries, Inc.* 199 F.3d 1295, 1301 (Fed. Cir. 1999).

The term "analyte" as used in the claims does not render the claims indefinite. First of all, Examiner's assertion that the generally accepted meaning of the term "analyte" refers to a single molecule or species is misplaced. A more complex definition of the term, similar to Applicants' definition, has been frequently used in the art. For example, the cited reference U.S. Pat. No. 5,149,626 ("Fleming") uses the term "analyte" to refer to proteins, as well as complex heterogeneous structures such as viruses, whole cells, subcellular particles, and substances binding thereto. See Column 5, lines 38-43 of Fleming. Additionally, the Examiner understands and accepts that the cited reference EP 0 171 150 ("Herzberg") refers to the term "analyte" as a mixture of antibodies and antigens even in the absence of a clear definition. See pages 15-16 of the Final Office Action.

Secondly, not only has the term "analyte" been used by others in the art to refer to complex heterogeneous structures, Applicants' intended use of the term "analyte" is clearly defined in the text on page 5, last paragraph to page 6, line 5 of the application, which states:

> *The analyte can be a homogeneous or heterogeneous population e.g. a heterogeneous antibody population, an antigen mixture or a mixture of an antigens and antibodies that may be different, the antigens and antibodies being derived from or induced by one or several pathogens. In the case of heterogeneous analyte population, the individual test areas bind a partial population of the analyte to be determined. Each of the analyte-specific receptors immobilized on a test area is different i.e., they bind, according to the invention, preferably to different epitopes of a homogeneous analyte such as an antigen,*

to different analyte subtypes such as antigen subtypes or/and to different analyte types such as different antigens or/and antibodies.

(Emphasis added). One of skill in the art would understand that as used in the instant application, the term "analyte" means a homogeneous population, or a heterogeneous population such as a mixture of antigens and/or antibodies. Thus, the recitation of the term "analyte" is not indefinite.

The term as used in the application would be further understood by one of skill in the art in the context of the specification. For example, the term "analyte" is referred to a mixture of HIV p24 antigen and p24 antibody (See page 17 second paragraph, and page 28, example 4); a mixture of different antibodies (page 17 last paragraph to page 18, first paragraph); a mixture of p24 antibody, RT antibody, and gp41 antibody (page 23 last paragraph); or a mixture of p24 antigen and gp41 antibody (page 26). All that is required is that one of skill in the art recognizes what definition is intended by the Applicant. The cited language on pages 5-6 and other examples and teachings throughout the specification clearly puts one of skill in the art on notice of Applicants' intended use of the term "analyte." Hence, the term "analyte" is not indefinite because one of skill in the art would understand the metes and bounds of the term as used in the claims. Therefore, Applicants respectfully request withdrawal of this rejection.

3. Paragraph 21 of the Office Action Mailed February 15, 2007

Claims 48 and 51-52 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for using the phrase "the epitope(s) of the analyte." Applicants respectfully traverse. Applicants have nevertheless amended the claims to remove the phrase "the epitope(s) of the analyte," and respectfully submit that the amendment has rendered the rejection moot.

4. Paragraph 22 of the Office Action Mailed February 15, 2007

Claims 44-52 and 73-74 are rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for the use of the term "epitope." Specifically, the Examiner asserts that Applicants use the term "epitope" to mean something other than its accepted meaning. Applicants respectfully disagree. Claim 74 is now canceled. The cancellation of claim 74 has

rendered this rejection moot. Furthermore, Applicants have amended claim 73, and respectfully submit that the amendment has rendered the rejection moot.

5. Paragraph 23 of the Office Action Mailed February 15, 2007

Claim 74 stands rejected under 35 U.S.C. § 112, second paragraph for lacking antecedent basis for the term "at least two epitopes." Applicants respectfully submit that cancellation of claim 74 has rendered the rejection moot.

F. The Claims Are Not Anticipated by Fleming

Claim 49 stands rejected under 35 U.S.C. § 102(b) as being unpatentable over Fleming, U.S. Patent No. 5,149,626 (hereinafter "Fleming"). Specifically, the Examiner asserts that Fleming teaches a solid phase for detecting multiple antigens in a sample. The Examiner alleges that the solid phase of Fleming reads on the solid phase of claim 49 for simultaneous separate multiepitope detection of an analyte in a sample, wherein the analyte encompasses a heterogeneous population. Applicants traverse the rejection.

As a threshold matter, the Federal Circuit has stated that for prior art to anticipate under section 102, every element of the claimed invention must be identically disclosed in a single reference. *Corning Glass Works v. Sumitomo Electric*, 9 U.S.P.Q.2d 1962, 1965 (Fed. Cir. 1989). The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q 193, 198 (Fed. Cir. 1983).

Claim 49, as amended, is directed to a solid phase for simultaneous separate multiepitope detection of an analyte, wherein the analyte comprises an antigen and an antibody directed against the same antigen. The solid phase of the current invention has a first receptor bound to the first test area and a second receptor bound to the second test area on the solid phase. Additionally, the first receptor binds specifically with the antigen, and the second receptor binds specifically with the antibody directed against the same antigen. Fleming merely relates to a solid phase with multiple antibodies attached thereto. Fleming does not teach or suggest a solid phase to which receptors for both an antigen and the antibody directed against the same antigen

bind. Thus, Fleming does not anticipate claim 49 because it does not teach or suggest each and every element of the claim. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) over Fleming.

G. The Claims Are Not Anticipated by Herzberg et al.

Claims 44, 47-49, 51-52, and 73 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Herzberg et al. (EP 0 171 150 A2, hereinafter "Herzberg") Specifically, the Examiner asserts that Herzberg teaches the detection of an analyte, such as Newcastle Disease or Whooping cough, by detecting both the antibodies and antigens associated with the disease. Applicants respectfully disagree.

Claim 44, as amended, is directed to a method for simultaneous separate multiepitope detection of an analyte in a sample, wherein a positive result is determined by a test area-specific cut-off value, and a positive result obtained on one test area is sufficient for indicating the presence of the analyte in the sample. The claimed method entails determining individually a cut-off value for each and every test area, and obtaining a positive result from the test area based on the test area-specific cut-off value. By using test area-specific cut-off value for each test area, it is possible to increase the sensitivity and specificity for each epitope of the analyte, and thus possible to increase the overall sensitivity of the assay for detecting the analyte.

Herzberg merely relates to a differential assay for a plurality of analytes in a sample. Herzberg does not teach or suggest the use of a test area-specific cut-off values for enhancing test sensitivity and specificity. The positive result in the Herzberg method is obtained based on a common cut-off value, which is determined and constrained by the non-specific binding of the worst component. Thus, the claimed method as set forth in claim 44 where the positive result on each test area is obtained by test area-specific cut-off value is novel in view of Herzberg.

Similarly, the solid phase of claim 49 is novel in view of Herzberg. Claim 49, as amended, is directed to a solid phase for use in a method of simultaneous multiepitope detection. The solid phase of claim 49 comprises a first receptor bound specifically with an antigen and a second receptor bound specifically with an antibody directed against the same antigen. Although Herzberg suggests it possible for a concomitant assay of both antigens and antibodies of a

pathogen on a single substrate, Herzberg does not teach or suggest a solid phase for the detection of an antigen and the antibody *directed against the same antigen.* Moreover, Herzberg does not teach or suggest a solid phase that comprises receptors for binding and detecting an antigen and an antibody *directed against the same antigen.* Further, Herzberg does not teach or suggest a kit including a solid phase of claim 49.

Thus, Herzberg does not anticipate claims 44, 49 and 51, and dependent claims thereon because it does not teach or suggest each and every element of the claims. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) over Herzberg.

H. The Claims Are Not Obvious based on Ekins *et al.* in view of Schonbrunner

Claims 49-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al., U.S. Patent No. 5,516,635 (hereinafter "Ekins"), in view of Schonbrunner, UK Patent Application Publication GB 2 313 666 A (hereinafter "Schonbrunner"). The Examiner bases the rejection on the assertion that Ekins teaches a solid support with receptors bound to each test area separated by an inert surface, and that Schonbrunner teaches a solid phase for the simultaneous detection of HIV antigen and HIV antibodies in a sample. Applicants respectfully traverse the rejection.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a); *see Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The ultimate determination of whether an invention is or is not obvious is based on underlying factual inquiries including: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations. *See Graham*, 383 U.S. at 17-18.

The MPEP clearly provides the criteria for establishing a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the

prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. The obviousness inquiry set forth in *Graham* focuses on whether the prior art as a whole teaches, suggests, or motivates one of ordinary skill in the art to make the invention and whether the skilled artisan would have a reasonable expectation of making and using it. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). The suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

In this case, the Office has not shown that the references or the knowledge generally available to one of ordinary skill in the art provide any suggestion or motivation to modify the reference or to combine reference teachings. Thus, Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness as the rejected claims. Applicants also submit that the Office cannot establish a *prima facie* case of obviousness of these claims in view of the present amendments to claim 49 because the references fail to teach or suggest all of the elements of the amended claims.

Claim 49, as amended, is directed to a solid phase comprising a first and a second test area, to which a first receptor and a second receptor bind, respectively. The first receptor binds specifically with an antigen and the second receptor binds specifically with an antibody *directed against the same antigen.* The Office concedes that Ekins fails to specifically teach different receptors specific for different epitopes bound to different test areas. While Schonbrunner does mention the use of different receptors specific for different epitopes, Schonbrunner does not teach spatially separated test areas having different receptors bound thereto that enable spatially separate detection of different epitopes.

Further, Schonbrunner does not disclose that the different receptors bind an antigen and an antibody *directed against the same antigen.* In fact, Schonbrunner explicitly teaches that the described method using the disclosed solid phase cannot simultaneously detect an antigen and an antibody directed against the same antigen. Schonbrunner states that "...any antigen analyte can be detected other than the antigens against which antibodies have been raised and which antibodies are selected to be detected as analytes by the present assay." See page 6, lines 19-21. (Emphasis added) Thus, the solid phase described in Ekins and Schonbrunner, either alone or in

combination, is structurally distinct from the claimed invention. The cited art, either alone or in combination, does not teach or suggest every element of the solid phase of claim 49.

Applicants submit that evidence of secondary consideration mandated by the Graham inquiry further bolster the non-obviousness of claim 49. Prior to the invention, there had been a long felt need for an assay system that would track closely the presence of an antigen of a pathogen, such as HIV, and the development of antibody to the antigen in an infected individual to allow early diagnosis of infection. However, such an assay system had not been possible due to the interference between the detection molecules. For example, the solid phases used in conventional combination tests do not allow simultaneous detection of HIV p24 antigen and anti-p24 antibody, but rather the p24 antigen combined with an anti-gp41 antibody. See page 17, second paragraph of the specification. The Applicants unexpectedly discovered that the interference effect can be avoided by using spatially separate test areas and by choosing compatible test format. The current application provides the first example in which an antigen and an antibody directed against the same antigen can be simultaneously detected on the same solid phase. The current invention provides a solution to a long felt need, the solution to which neither Ekins nor Schonbrunner could provide. Thus, the claimed invention is not obvious to one of skill in the art over Ekins in view of Schonbrunner.

Applicants further submit that the cited art, alone or in combination, does not teach every element of dependent claim 50, the kit claim 51 comprising the solid phase of claim 49, and dependent claim 52 thereon. Thus, the Office has not established a *prima facie* case of obviousness against claims 49-52 based on Ekins and Schonbrunner. Accordingly, withdrawal of rejections under 35 U.S.C. § 103(a) over Ekins and Schonbrunner is respectfully requested.

I. The Claims Are Not Obvious from Ekins, Schonbrunner and Lancaster

Claims 44-46, 48 and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins, in view of Schonbrunner, and in further view of Lancaster, U.S. Patent No. 3,568,735 (hereinafter "Lancaster"). Applicants respectfully traverse the rejection.

Claim 44, as amended, is directed to a method for simultaneous separate multiepitope detection of an analyte in a sample, wherein a positive test result is determined by a test area-specific cut-off value, and wherein a positive result on one test area is sufficient to indicate the

presence of the analyte in the sample. Schonbrunner merely relates to a method of detecting multiple epitopes of an analyte in a sample. Schonbrunner does not teach or suggest a method for simultaneous separate multiepitope detection of an analyte in a sample where the different receptors for different epitopes are bound to distinct and spatially separate test areas. Additionally, Schonbrunner does not teach or suggest a method for simultaneous separate multiepitope detection wherein the positive result is determined by a test area-specific cut-off value; rather, Schonbrunner discloses the use of a universal cut-off value for all the receptor-epitope interactions. Further, Schonbrunner does not teach a method for simultaneous separate multiepitope detection wherein the positive result obtained on one test area is sufficient to indicate the presence of the analyte in the sample.

Additionally, unexpected results as evidence of secondary consideration set forth in the Graham inquiry further bolster the non-obviousness of the subject matter of claim 44. Applicants unexpectedly discovered that detection using spatially separate test areas with individualized cut-off value produces enhanced sensitivity in analyte detection. The test area-specific cut-off value is possible only when receptors specific for different epitopes are bound to spatially separate test areas on the solid phase. As a result, the cut-off value for each test area can be determined individually. Once the detection limit for each epitope can be determined individually, the detection of only one epitope on one test area is sufficient to indicate the presence of the analyte.

The method described by Schonbrunner, however, uses a solid phase to which different epitopes are immobilized together on one test area. Similar assay is used in the Enzymun® HIV test described in the specification as a comparative example to the current invention. See Examples 2 and 3 of the current application. Comparison of the Enzymun method, which is similar to Schonbrunner's method, with the current invention reveals that method based on the binding of different epitopes to one single test area requires higher analyte concentration and produces less sensitive results in detecting a target analyte.

Although Ekins discloses a solid phase with different test areas, nothing in the cited references or in the knowledge of one or ordinary skill in the art would motivate a skilled artisan to combine Ekins with Schonbrunner and modify the cited art to arrive at the current invention. Neither Ekins nor Schonbrunner recognizes the benefit of using spatially separate test areas, or the benefit of using a test area-specific cut-off value. In fact, even in combination, the cited art does not teach or suggest the use of test area-specific cut-off values, and thus does not teach or

suggest every element of the claim. It is the Applicants' discovery that a method using spatially separate test areas and test area-specific cut-off values produces superior detection results. See Example 2 of the current application. Thus, it would not have been obvious the claimed method in view of Ekins and Schonbrunner.

Lancaster does not cure the defect. Lancaster merely relates to a simultaneous application of sample to the test areas. Lancaster does not teach or suggest a method for simultaneous separate multiepitope detection where the positive result is obtained by a test area-specific cut-off value and where a positive result obtained on one test area is sufficient to indicate the presence of the analyte.

Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness because the cited art, either alone or in combination, does not teach every element of the claims. Reconsideration and withdrawal of rejection under 35 U.S.C. § 103(a) over Ekins, in view of Schonbrunner and Lancaster is earnestly requested.

J. The Claims Are Not Obvious based on Ekins, Schonbrunner, Lancaster, and O'Connor et al.

Claims 47 and 74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins, in view of Schonbrunner and Lancaster, and further in view of O'Connor et al. U.S. Patent No. 5,627,026 (hereinafter "O'Connor"). Specifically, the Examiner asserts that claim 47 is obvious because O'Connor teaches the use of a control well on a microtiter plate in an ELISA assay. Applicants respectfully traverse these rejections. Claim 74 is now canceled. The cancellation has rendered the rejection moot.

Claim 47, as amended, is directed to a method for simultaneous separate detection of multiepitope of an analyte where the positive result is obtained by a test area-specific cut-off value, and wherein the solid phase further comprises a control area for detecting false results caused by interferences. As stated above, none of the references Ekins, Schonbrunner, and Lancaster, either alone or in combination, renders the underlying claimed method obvious. O'Connor does not cure the defect. O'Connor merely relates to the use of a control spot on the plate. However, O'Connor does not teach of suggest the use of test area-specific cut-off values in determining a positive result in analyte detection. O'Connor states that "[a]nything 3 times

greater in absorbance intensity than the negative control is regarded as a positive sample." See column 9, lines 23-24. Such a generalized determination of cut-off values fails to teach or suggest a test area-specific cut-off value that is determined individually for each test area. Further, according to O'Connor, control spots only serve to determine a non-specific background signal caused by the detection reagent itself. O'Connor does not teach or suggest a control area for detecting false results caused by interference as recited in amended claim 47.

Without a teaching of all of the claimed elements in the underlying independent claim 44, the obviousness rejection of claim 47 cannot stand. Withdrawal of rejection is thus earnestly solicited.

K. Double Patenting

Claims 44-52 and 73-74 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,815,217 ("the '217 patent"). The cancellation of claim 74 has rendered the rejection moot.

The subjects of the '217 patent and the present application are patentably distinct. Claims 1-34 of the '217 patent are directed to a device, a method, and a kit for detecting an analyte in a sample containing at least one interfering substance. Specifically, claims 1-18 of the '217 patent are directed to an assay device for use in determination of an analyte in a sample that comprises at least one interfering substance, said device comprising a solid phase support; a test area comprising test area components wherein the at least one interfering substance non-specifically binds to one or more test area components; and a control area comprising control area components in a separate defined region of the support, wherein the control area components are the same as at least some of the test area components, and wherein the at least one interfering substance non-sppecifically binds to one or more control area components.

Claims 19-33 of the '217 patent are directed to an assay method for determining an analyte in a sample that comprises at least one interfering substance, said method comprising applying the sample to the solid support that comprises a test area and a control area, applying a marker to the solid phase support to generate a detectable signal; and measuring the signal generated by the marker in the test area and in the control area.

Claim 34 of the '217 patent is directed to a kit for use in the determination of an analyte in a sample that comprises at least one interfering substance, said kit comprising a solid phase support including a test area and a control area; and a marker capable of binding to the analyte and to the at least one interfering substance.

The present claims 44-48, and 73, on the contrary, concerns a method for simultaneous separate multiepitope detection of an analyte in a sample, the analyte comprising at least two epitopes, comprising the steps of providing a solid phase comprising a non-porous support, a first and a second spatially separate test area, and at least a first and a second receptor, the first receptor binding specifically with the analyte via a first epitope and the second receptor binding specifically with the analyte via a second epitope, the first receptor bound directly or indirectly to the first test area and the second receptor bound directly or indirectly to the second test area; contacting the sample with the solid phase and with a detection reagent comprising one or more of a third receptor that binds specifically with the analyte and that is bound directly or indirectly to a signal generating group; and spatially separately determining presence or amount of the signal generating group on the first and second test areas, wherein said signal generating group is bound to the first test area or the second test area or the first and second test areas via said analyte, as a measure of the analyte in said sample, wherein a positive test result obtained via a test area-specific cut–off on one test area is sufficient for indicating the presence of the analyte in said sample.

Applicants submit that claims 1-34 of the '217 patent and claims 44-52 and 73 of the instant application are patentably distinct. The subject matter of claims 1-34 of the '217 patent concerns the use of control spots; whereas the subject matter of claims 44-52 and 73 of the current invention concerns simultaneous separate detection of multiepitope of an analyte in a sample based on test area-specific cut-off values. In view of the differences between the present application and claim 1-34 of the '217 patent, Applicants respectfully request that the double patenting rejection be withdrawn.

L. Conclusion

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the Applicants' undersigned representative

at (312) 913-2126 if the Examiner believes that this would be helpful in expediting prosecution of this application.

Date: June 15, 2007

Respectfully,

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